

REMARKS

The Obviousness-type Double Patenting Rejection

The applicants thank the examiner for pointing to the appropriate section of the MPEP describing filing a proper terminal disclaimer. Upon review, it is the applicants' belief that the examiner is requesting a terminal disclaimer be filed with respect to the "primary reference" upon which the rejection is based, *i.e.*, US Patent 6642363 which claims earliest priority of US patent application Serial Nos. 60/026362 and 60/02646, both filed September 19, 1996. If this belief is correct, the applicants respectfully request notification of the same.

The rejection under 35 USC §103

The examiner maintained the rejection of claims 14, 17, 18, 48, and 118-130 for reasons set out in the previous office action. In response to the applicants' previous arguments, the examiner acknowledged the requirement that the cited art provide motivation to the worker of ordinary skill to modify the disclosures to produce the invention as claimed.

The examiner continued stating,

In this case, Shapiro clearly teaches the successful use of porous alginate sponges for the cell culture and transplantation. Furthermore Fang clearly provides motivation to incorporate nucleic acid molecules in the alginate sponge as taught by Shapiro in order to transduce cells. Furthermore one would have had a reasonable expectation of success in doing so, since genetic modification of host cells by transplanting a porous matrix has been routine in the art at the time the instant invention was made. In addition given the scope of a molecule that mediates a cellular interaction the alginate matrix inherently contains alginate chains section bonded to various oligosaccharides that mediate cellular interaction (see Kawada). The phrase "mediating cellular interaction via alginate chain section [action p.5] refers to "matrix is capable of mediating cellular interaction via alginate chain section" in view of limitation recited in claim 14. Thus the invention as

claims is *prima facie* obvious in view of cited prior art of record.

The applicants respectfully disagree. The composition of claim 48 is a porous, modified alginate matrix comprising at least one nucleic acid in non-covalent association with the matrix, and further modified by covalent bonding to include to at least one molecule that mediates cellular interaction. With respect to the molecule that mediates cellular interaction, the specification teaches at, for example, p. 118, lines 6 through 21, that this molecule is added to the matrix and in one aspect, it is added by covalent modification of a polysaccharide. Thus, the amendment to claim 48 herein clarifies what was previously implicit; the matrix is modified to include the cell interaction molecule. Moreover, clarification by amendment to the subject matter of the claims renders moot the examiner's assertion that a component in the claimed composition, a molecule that mediates cellular interaction, inherently exists on alginate. Whatever moieties exist on naturally-occurring are irrelevant in view of the fact that alginate in the claimed composition must be modified to include some other cell interaction molecule.

Inasmuch as the combined art cited by the examiner fails to disclose each and every limitation of the invention as claimed (*see* MPEP §706.02(j)), the applicants submit that the rejection must be withdrawn.

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Respectfully submitted,

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